

201-15907

**PCRM** P H Y S I C I A N S  
C O M M I T T E E 5100 WISCONSIN AVENUE, N.W., SUITE 400  
F O R WASHINGTON, DC 20016  
R E S P O N S I B L E T: (202) 686-2210 F: (202) 686-2216  
M E D I C I N E PCRM@PCRM.ORG WWW.PCRM.ORG

May 19, 2005

Mr. Stephen Johnson, Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building, 1101-A  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

RECEIVED  
OPPT CDIC  
05 MAY 20 AM 10:03

Subject: Comments on the HPV Test Plan for the Dinonylnaphthalene category

Dear Administrator Johnson:

The following comments on King Industries' test plan for the chemical category dinonylnaphthalene are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

King Industries submitted their test plan on Dec. 27, 2004, for the chemical category dinonylnaphthalene, which consists of four chemicals: diisononylnaphthalene (CAS No. 63512-64-1), dinonylnaphthalene sulfonic acid (CAS No. 25322-17-2), dinonylnaphthalene sulfonic acid, barium salt (CAS No. 25619-56-1), and dinonylnaphthalene sulfonic acid, calcium salt (CAS No. 57855-77-3). These chemicals are used as additives in industrial lubricants, greases, metalworking fluids, industrial coatings, and rust preventives. The sponsor has utilized structure activity relationship programs and models, to estimate physiochemical properties. However, King Industries does not use this methodology for estimating ecotoxicity and proposes to conduct an acute fish test (OECD 203) with dinonylnaphthalene sulfonic acid, which will result in the death of 40-120 fish. In any case, acute fish testing should not be conducted, as the log  $K_{ow}$  of dinonylnaphthalene sulfonic acid is 9.0, and the log  $K_{ow}$  values of the other three dinonylnaphthalenes are even higher, ranging from 10.96 to 23.3. The EPA has stated that acute fish tests are inappropriate for compounds with log  $K_{ow}$  values above 4.2 (*Federal Register*, 2000).

We also disagree with King Industries' proposal to conduct a repeated dose/reproduction/developmental screen (OECD 422), which will result in the deaths of at least 675 animals. King Industries further states that the requirement for developmental and/or reproductive toxicity tests will be decided on the basis of the results of this test, yet there is absolutely no need for further reproductive or developmental toxicity tests once an OECD 422 has been carried out.

Although no data were located on the subchronic, genetic, reproductive, or developmental hazards of these chemicals, we have serious concerns with the performance of additional mammalian toxicity testing with dinonylnaphthalene sulfonic acid, barium salt. In that oral administration is not a likely route of exposure for humans, a dermal study would be the most appropriate route for testing. However, based on existing acute toxicity findings, this chemical appears to be a dermal irritant and animal testing via OECD 422 is inappropriate via the dermal route. This is an important point because chemicals that are classified as irritating will not likely cause systemic toxicity at doses that do not also cause significant local effects. It would therefore be difficult to infer causation in the event of a positive result with dinonylnaphthalene sulfonic acid, barium salt. We urge King Industries to conduct a thoughtful analysis of the toxicity of dinonylnaphthalene sulfonic acid, barium salt to determine whether any new testing will result in useful information. The EPA has also stated that participants "may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested" and "as with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant." (Wayland, 1999; *Federal Register* 2000).

Although we support the formation of a category for these four chemicals, we do not believe additional testing is warranted for the purposes of the HPV program. We would also like to inquire if King Industries has tried to contact Henkel Consumer Adhesives about possible toxicity data on dinonylnaphthalene sulfonic acid, barium salt. This chemical is component of the commercially available household product, Naval Jelly Rust Preventer.

Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at [meven@pcrm.org](mailto:meven@pcrm.org).

Sincerely,

Megha Even, M.S.  
Research Analyst

Chad B. Sandusky, Ph.D.  
Director of Toxicology and Research

## References

EPA. Data collection and development on high production volume (HPV) chemicals. *Federal Register*, Vol. 65, No. 248, Dec. 26, 2000.

Wayland SH. Letters to manufacturers/importers. 1999.  
<http://www.epa.gov/chemrtk/ceoltr2.htm>.